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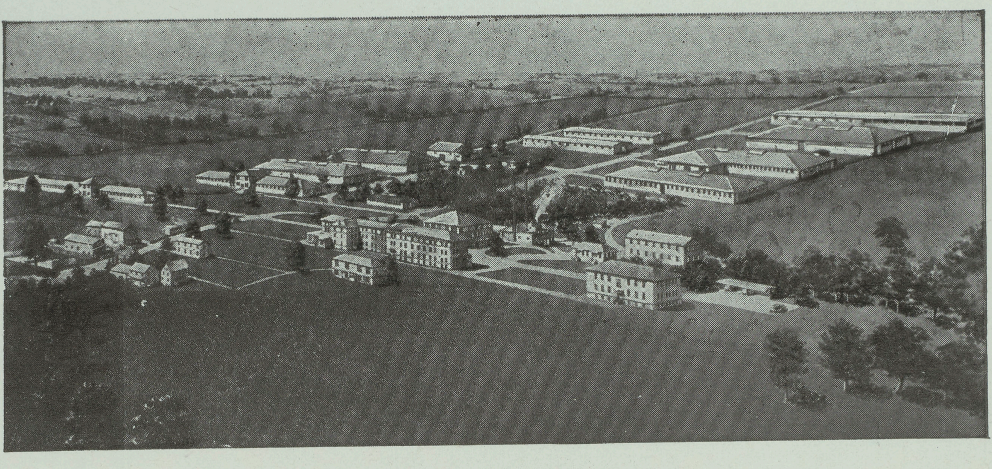
Bacillus Acidophilus Milk

Lederle



LEDERLE ANTITOXIN LABORATORIES, PEARL RIVER, ROCKLAND COUNTY, N. Y., WHERE BACILLUS ACIDOPHILUS MILK (LEDERLE) IS PRODUCED

Chans

Bacillus Acidophilus Milk

Lederle

Accepted by the Council on Pharmacy and Chemistry of the American Medical Association for New and Non-Official Remedies on January 26th, 1923.

Intestinal Toxemia

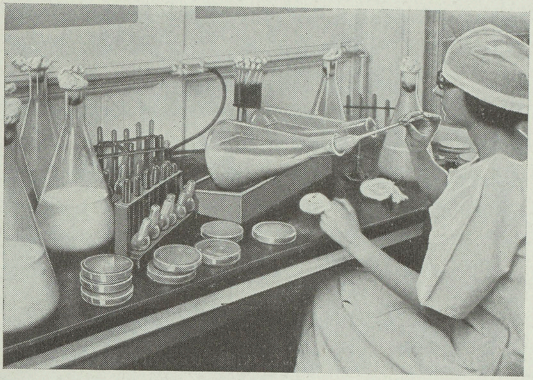
Intestinal toxemia is a more frequent condition than has usually been credited; for it is associated with many, if not most, digestive disturbances. It results from toxic substances produced during decomposition and putrefaction of foods due to the activity in the intestine of putrefactive bacteria, such as Bacillus coli, Bacillus welchii, Bacillus proteus, Bacillus putrificus, and other toxicogenic intestinal microorganisms. The absorption of toxic substances from the lower bowel gives rise to changes in the liver, brain, kidneys and blood vessels. Thus, it will be seen that the effects of intestinal toxemia are far reaching. Some symptoms of this condition include decreased peristaltic action of the intestines with obstinate constipation and intestinal gas; persistent headache of the migraine type; periodical attacks of abdominal pain, distension of stomach or intestine with gas, accompanied by belching and vomiting; again, there may be depression, fatigue, aching limbs, ringing in the ears, and dizzy spells; or, mucous colitis with blood and mucus in the stools; or, chronic diarrhea; or, some skin manifestation such as urticarial (hive-like) rash.

Intestinal Antisepsis

Intestinal antisepsis has received considerable attention, and many attempts have been made to reduce the number of putrefactive bacteria in the intestine by administering various drugs. The use of such intestinal antiseptics has proved disappointing and, after years of observation, it is the consensus of opinion that disinfection of the digestive tract with drugs is of little value in causing a diminution in the number of putrefactive bacteria of the intestine; even sterilization of the food has had little or no influence on the number of intestinal bacteria.

Bacillus Acidophilus

In addition to the putrefactive types of bacteria in the intestine, there is also usually



PREPARATION OF SEED CULTURES OF BACILLUS ACIDOPHILUS IN MILK

present a lactic acid-producing organism called Bacillus Acidophilus. During early childhood, or as long as milk forms a large part of the diet, this bacillus constitutes almost the entire bacterial content of the intestine. In normal adults, the Bacillus Acidophilus constitutes from none up to 5 or 6 per cent of the living bacteria present in the intestine; the remainder being composed of a variety of putrefactive types.

The larger the number of Bacillus Acidophilus in the intestine, the less putrefactive bacteria will be present and, therefore, the less putrefaction and intestinal toxemia that will occur. This fact encouraged the belief that, by introducing cultures of lactic acid bacilli into the intestine, it would be possible to arrest the growth of putrefactive and other pathogenic bacteria and thus control intestinal toxemia.

Milk Cultures of Bacillus Acidophilus

Bacillus Acidophilus lends itself to implantation and colonization within the human digestive tract. Milk has proved to be the most favorable medium for this organism because it contains about 4 percent of lactose (milk-sugar) in solution, and lactose promotes the growth of Bacillus Acidophilus. Furthermore, in milk cultures there is present a most remarkable combination of inorganic salts and proteins which are capable of acting as buffers for the lactic acid produced by the Bacillus Acidophilus, thus insuring the life of the culture to a degree so far unattainable in any other culture medium. Hence, the adoption of milk as the medium for the growth and administration of these organisms.

In order to make certain, however, that the

Bacillus Acidophilus will successfully colonize within the intestinal tract, cultures of this organism must not be kept too long on artificial media before being introduced into the intestine; for long cultivation of the Bacillus Acidophilus outside the human body may so modify its adaptability to the intestinal conditions that it would not fulfill its intended purpose.

Bacillus Acidophilus Milk (Lederle)

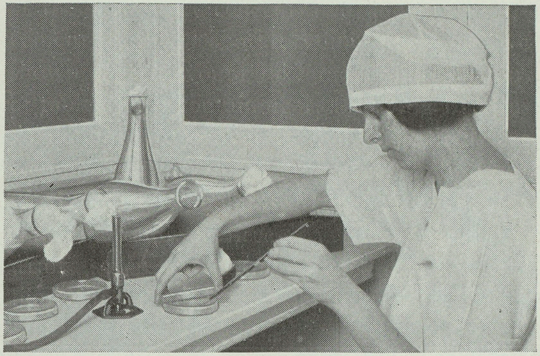
It will be seen from the above that Bacillus Acidophilus Milk must not be confused with the beverage sour milks. On the contrary, when properly prepared, it is a valuable therapeutic agent from whose use the physician may expect certain definite results.

Bacillus Acidophilus Milk (Lederle) is prepared with cultures of Bacillus Acidophilus that are freshly isolated from the intestinal contents as frequently as may be necessary to insure their adaptability to intestinal implantation and throughout its preparation this product is given the same detailed scientific care in our laboratories that is accorded to Diphtheria Antitoxin or any other biological product intended for use in man.

In the routine preparation of each batch of Bacillus Acidophilus Milk (Lederle), there are four separate and complete bacteriological studies. First, the original stock cultures are examined for purity of growth by agar plates and by fermentation tests in special sugar media. Second, the growth in a single flask from the stock culture is likewise examined. Third, twenty or more flasks are inoculated from this single flask. The growth in these flasks is examined as above. These flasks contain approximately 5 per cent of the volume of the batch of milk in the tanks to be inoculated for the finished product. Fourth, the finished bottled Bacillus Acidophilus Milk (Lederle) is examined in a similar manner. Each cubic centimeter of Bacillus Acidophilus Milk (Lederle) contains not less than fifty million of viable organisms (*B. acidophilus*) at the time of sale.

Bacillus Acidophilus Milk
vs.
Tablets and Broth Cultures

It must be admitted that best results from Bacillus Acidophilus therapy are not likely to



INOCULATING WHEY AGAR PLATES WITH SEED CULTURE OF BACILLUS ACIDOPHILUS TO DETERMINE ITS PURITY

be obtained by the simple administration of small amounts of the culture in tablet form, in capsules, in broth culture, or in any other of the supposedly concentrated and more convenient forms. Laboratory investigations have shown that it would take more than 20 tons of tablets each containing 1,000 living Bacillus Acidophilus to convey as many bacilli as are contained in one quart (the usual daily dose) of Bacillus Acidophilus Milk. And further, that it would be necessary for a patient to drink seven or eight gallons daily of the liquid broth cultures to obtain as many Bacillus Acidophilus as are contained in one quart of Bacillus Acidophilus Milk.

If it were possible, by the administration of small doses of a broth culture of the Bacillus Acidophilus, to achieve satisfactory clinical results, it would be most desirable. Again, if a sufficient quantity of living Bacillus Acidophilus could be maintained in tablets to permit of results that would be clinically and bacteriologically successful that too would be desirable. The only reason that milk is used as the medium for carrying the culture is that milk has been proved to be well adapted for the growth and maintenance of the Bacillus Acidophilus in the lower bowel where the bacilli will thrive and eradicate the putrefactive bacteria. While it is admitted that milk is bulky and is not acceptable to all patients, yet this medium has given by far the most dependable results in Bacillus Acidophilus therapy.

Dosage

In putrefactive conditions, implantation of the Bacillus Acidophilus is often assisted by the preliminary use of a cathartic. Bacillus Acidophilus Milk (Lederle) may then be prescribed, preferably before meals, as follows:

First day, 6 glassfuls (8 oz. each) without other food.

Second day, 6 glassfuls (8 oz. each) with light, farinaceous diet.

Third day, 6 glassfuls (8 oz. each) with regular, full diet.

Thereafter, 3 glassfuls (8 oz. each) daily.

Milk Sugar (Lactose)

In very obstinate cases, it may be difficult to establish the Bacillus Acidophilus in the intestinal tract. In such cases, the constipation may even be aggravated during the first two or three days' treatment with Bacillus Acidophilus Milk and it may be advisable for the patient to take a laxative; but the constipation can usually be corrected if sufficient lactose and Bacillus Acidophilus Milk are taken daily.

For this purpose, from 6 to 10 heaping teaspoonfuls of lactose (milk sugar) may be added to each glassful of the milk. The lactose may be added directly to the milk and thoroughly mixed with it; but many patients perfer to dissolve the milk-sugar in water and then drink the sugar solution separately, so that the flavor and palatability of the Bacillus Acidophilus Milk will not be altered.

Advantages

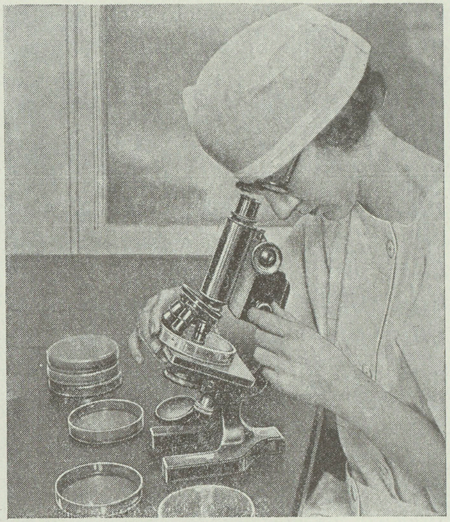
The following points are worthy of special emphasis:

(1) Bacillus Acidophilus Milk (Lederle) contains a young culture of living Bacillus Acidophilus. This product is particularly potent in bringing about the desired transformation of undesirable and unhealthful bacterial types in the intestine to non-putrefactive types consisting chiefly of Bacillus Acidophilus which is favorable to the normal, healthy functioning of the intestine; thus tending to promote the general bodily health.

(2) Bacillus Acidophilus Milk (Lederle), being prepared from whole milk, contains sufficient lactose for the Bacillus Acidophilus therapy of diarrhea. When used for correcting chronic constipation, the efficiency of Bacillus Acidophilus Milk will be enhanced by the addition of lactose as explained above.

(3) Bacillus Acidophilus Milk (Lederle) is tolerated by many who are unable to assimilate an ordinary diet.

(4) Bacillus Acidophilus Milk (Lederle) retains its therapeutic activity, permitting of its general distribution.



MICROSCOPICAL EXAMINATION OF WHEY AGAR PLATES OF BACILLUS ACIDOPHILUS

Clinical Reports

One of the most comprehensive studies of the value of Bacillus Acidophilus Milk in gastrointestinal disorders is that of Clark and Perry. They reported (*New York Medical Journal and Record,* December 19, 1923) observations on 84 patients extending over a period of 18 months. Fifty patients had chronic constipation which had persisted for many years. Administration of Bacillus Acidophilus Milk with lactose produced a distinctly laxative effect. A group of 27 patients complained of such symptoms as a sense of fullness, of heaviness, of shifting abdominal pain, so-called "gas pain," and of explosive passage of gas, together with drowsiness and a tired feeling. Of this number, 23 showed marked improvement after treatment. Five elderly patients who suffered with intestinal gas and bloating obtained marked relief under Bacillus Acidophilus Milk treatment. Six patients with chronic diarrhea, which had lasted from one month to six years, and one patient with tropical sprue of two years' duration, made rapid and complete recoveries under Bacillus Acidophilus Milk therapy and remained well at the end of one year; also three out of four cases of chronic eczema cleared up under this treatment.

At Gaylord Farm in Wallingford, Connecticut, Bacillus Acidophilus Milk treatment of gastrointestinal complications in tuberculosis was employed by MORRIS. He reported (*Journal A. M. A.,* July 14, 1923) six cases of chronic diarrhea, all of which were relieved. Improvement occurred in nine out of thirteen cases of chronic digestive disorders, characterized by gastric and intestinal gas, nausea and vomiting, sensation of fullness and discomfort and loss of appetite. There was improvement also in three out of four cases of obstinate constipation. The daily amount of Bacillus Acidophilus Milk given to each patient was one quart. The duration of the treatment varied from 10 days to one year; the average length of treatment being three and one-half months.

A group of patients suffering from mucous colitis, constipation and diarrhea were treated with Bacillus Acidophilus Milk by CHEPLIN, POST and WISEMAN (*Boston Medical and Surgical Journal,* September 20, 1923). They found that in constipation, Bacillus Acidophilus Milk produces beneficial results by regulating the bowel movements; while in diarrhea and mucous colitis its effects are shown by a gradual restoration of formed movements and the disappearance of mucus.

At the New York State Psychiatric Institute, KOPELOFF studied the effect of Bacillus Acidophilus Milk treatment in cases of constipation and diarrhea. In a series of 30 constipated subjects, the number of normal bowel movements was significantly increased. Patients were observed for from one week to about one year after treatment, and almost without exception all had more normal bowel movements after than before treatment with Bacillus Acidophilus Milk. The addition of lactose did much to enhance the beneficial effects. Two cases of diarrhea were successfully treated by the administration of Bacillus Acidophilus Milk but without the addition of lactose.

Packages

Bacillus Acidophilus Milk

Lederle

Code Word	
LACIDOF	Six 8-ounce bottles.
LACK	Three 1-quart bottles.

LEDERLE
ANTITOXIN LABORATORIES
NEW YORK

Printed in U. S. A.